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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,150	09/21/2005	Yuko Taniike	071971-0366	7373

53080 7590 08/11/2008

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EXAMINER	
DAMRON, ANITA B	
ART UNIT	PAPER NUMBER
4112	
MAIL DATE	DELIVERY MODE
08/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,150	TANIIKE ET AL.	
	Examiner	Art Unit	
	ANITA DAMRON	4112	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/21/05 and 2/4/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Summary

1. This is the initial Office Action based on the 10/550,150 application filed September 21, 2005.

2. Claims 1-12 are pending and have been fully considered.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. ***Claims 1-5 and 8-10 are rejected under 35 U.S.C. 102(b) as being anticipated by DOUGLAS et al (US 5,843,691).***

5. Regarding Claim 1, DOUGLAS teaches **a biosensor for measuring a test substance included in a comprising:** *(an elongated multilayer reagent test strip for measuring the concentration of analyte in a sample of biological fluid that is applied to the strip, comprising)* in claim 1,

a. **a substrate;** (*a bottom layer with a through hole for accepting the sample)* in claim 1,

b. **a sample receiving section provided on said substrate to which said sample is supplied;** *(a membrane layer, having a sample side)* in claim 1,

c. **a reagent section provided in said sample receiving section and including a reagent to be reacted with said test substance** *(a direct-reading reagent test strip for measuring concentration of an analyte in a biological fluid. The key element of such a*

test strip is a porous matrix that incorporates a testing reagent) in the specification column 5 lines 56-61,

d. **a moisture absorbing material that is changed in color through absorption of moisture,** *(test strip is a porous matrix that incorporates a testing reagent that undergoes a color change in response to the analyte in a biological fluid sample that is applied to the strip)* in the specification column 5 lines 58-61,

e. **wherein a degree of degradation of said reagent is shown on the basis of a proportion of a portion of said moisture absorbing material changed in color.** *(As the sample passes through the matrix, reaction with the reagent causes a light-absorbing dye to be formed or decomposed in the void volume near the testing side, thereby substantially affecting reflectance from the matrix)* in the specification column 6 lines 22-25.

6. Regarding product and apparatus claims, when the structure recited in the reference is substantially identical to that of the claims, claimed properties or functions are presumed to be inherent (see MPEP § 2112.01).

Regarding composition claims, if the composition is physically the same, the composition must have the same properties (see MPEP § 2112.01).

The Courts have held that it is well settled that where there is a reason to believe that a functional characteristic would be inherent in the prior art, the burden of proof then shifts to the applicant to provide objective evidence to the contrary. See *In re Schreiber*, 128 F.3d at 1478, 44 USPQ2d at 1478, 44 USPQ2d at 1432 (Fed. Cir. 1997).

7. Regarding Claim 2, DOUGLAS teaches **the biosensor of claim 1, further comprising a cover for covering said moisture absorbing material, wherein a part of said moisture absorbing material is exposed** *(The strip may also include a cover, which includes an opening through which sample may be introduced)* in the specification column 2 lines 22-24.

8. Regarding Claim 3, DOUGLAS teaches **the biosensor of claim 2, wherein the degree of degradation of said reagent is shown on the basis of a degree of color change of a portion of said moisture absorbing material that is present at a given distance from the exposed part** *(The hydrogen peroxide, preferably catalyzed by a peroxidase, reacts either directly or indirectly to form or decompose an indicator dye that absorbs light in a predetermined wavelength range. Preferably, the indicator dye absorbs strongly at a wavelength different from that at which the testing reagent absorbs strongly. The oxidized form of the indicator may be the colored, faintly colored, or colorless final product that evidences a change in color of the testing side of the matrix. That is to say, the testing reagent can indicate the presence of analyte in a sample by a colored area being bleached or, alternatively, by a colorless area developing color)* in the specification column 7 lines 18-29 and is covered with said cover *(The strip may also include a cover, which includes an opening through which sample may be introduced)* in the specification column 2 lines 22-24.

9. Regarding Claim 4, DOUGLAS et al. **teaches the biosensor of claim 1, wherein said reagent includes an enzyme** *(Preferred components for converting glucose to hydrogen peroxide include glucose oxidase, an enzyme)* in the specification column 6 lines 60-61.

10. Regarding Claim 5, DOUGLAS teaches **the biosensor of claim 4, wherein said reagent section further includes an electron mediator.** *(indicator dye or dye couple is [3-methyl-2-benzothiazolinone hydrazone]N-sulfonyl benzenesulfonate monosodium combined with 8-anilino-1-naphthalene sulfonic acid ammonium (MBTHSB-ANS))* in claim 14.

11. Regarding Claim 8, DOUGLAS teaches **the biosensor of claim 1, wherein said moisture absorbing material is in the shape of a sheet** *(a membrane layer, having a sample side facing the bottom layer and a testing side opposite to it, and having arrayed along its length a plurality of discrete bibulous assay areas separated by a non-bibulous region)* in the specification column 3 lines 8-12 and see figure 3.

12. Regarding Claim 9, DOUGLAS teaches **the biosensor of claim 1, further comprising a covering member made of a light blocking material and formed over said substrate for covering said sample receiving section** *(Since the assay areas, when they contain the preferred reagent, slowly undergo a color change when exposed to light or oxygen and since the optional timer is sensitive to moisture, strips are preferably packaged in an opaque oxygen- and moisture-impermeable enclosure, such as a sealed foil wrap. If strips are individually packaged, the strip may remain in the peeled-open wrap during use)* in the specification column 11 line 66 through column 12 line 3.

13. Regarding Claim 10, DOUGLAS teaches **the biosensor of claim 8, wherein said moisture absorbing material in the shape of a sheet is provided on a face of said substrate opposite to a face thereof on which said sample receiving section is provided, and a sheet for covering said moisture absorbing material is provided on said moisture absorbing**

material *(applying the sample to a reagent test strip that comprises: a bottom layer with a through hole for accepting the sample and a membrane layer, having a sample side facing the bottom layer and comprising a plurality of bibulous assay areas that each change color when contacted with fluid containing at least a predetermined amount of analyte)* in claim 31 and *(the intermediate layer comprises a thermoplastic sheet)* in claim 19.

14. ***Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by NANKAI et al. (US 5,266,179).***

15. Regarding Claim 11, NANKAI et al. teaches **A biosensor measuring apparatus for measuring a test substance included in a sample** *(quantitative analysis system for measuring a specific component in biological body fluid)* in claim 1 **by using a biosensor including a substrate** *(disposable sensing means including a substrate)* in claim 21; **a sample receiving section provided on said substrate and containing a reagent section including a reagent to be reacted with said test substance** *(disposable sensor means, including a capillary shaped portion and an enzyme portion, for receiving a sample liquid for analysis)* in claim 7 and *(a reaction layer, including an enzyme and a mediator)* in claim 21; **and a moisture absorbing material changed in color through absorption of moisture** *(excessive wiping or rinsing damages the test paper or washes out colored reagent)* in the specification column 2 lines 8-10;

f. **a detecting section including a light source for irradiating said moisture absorbing material with light and a photo detecting device for receiving incident light emitted from said light source through said moisture absorbing material** *(in this case, when a substance 14 related to the generation of a signal substance (a combination of urate and dissolved oxygen) reaches a signal substance generator*

(uricase-labeled specific binding substance) 10 in a channel "b", a signal substance (hydrogen peroxide) 12 is formed. When the signal substance 12 reaches and detection means c1 or c2 (peroxidase-immobilized part) it changes a substance related to the generation of a signal (orthodianisidine) to generate a signal (coloration).
(98) Thereafter, coloration after or until a predetermined time elapse is measured at each detection means "c" by detecting absorbance or reflected light of the color or visually observing the color.) in the specification column 18 lines 55-67.

g. **a measuring section connected to said detecting section for measuring an optical characteristic of said incident light and for determining a degree of degradation of said reagent included in said reagent section of said biosensor on the basis of said optical characteristic of said incident light.** *(examples of signals include electron transfer, which is measurable by electrochemical means, fluorescence which is measurable using a fluorophotometer, luminescence which is measurable using a luminometer and coloring which is measurable by visual judgment or using a reflect-meter. The electrochemical means is most preferable, because it can measure signals even in total blood and the like samples which contain blood cell components, hemoglobin and the like)* in the specification column 7 lines 59-67. *(According to the present invention, a plurality of the detection means are arranged at different positions along the liquid sample flowing direction in the channel, in order to enable accurate assay by minimizing influences of other factors than the concentration of the substance to be assayed, such as contaminants, viscosity and the like sample properties, reaction (development) temperature and the like environmental conditions and enzyme activity*

reduction, substrate decomposition and the like changes in the reagents used in the assay system.) in the specification column 8 lines 56-65.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. ***Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over DOUGLAS et al (US 5,843,691) in view of YAMAUCHI et al. (US 5,723,345).***

19. Regarding Claim 6, DOUGLAS et al. teaches **the biosensor of claim 5** according to claims 1-4.

However DOUGLAS et al. does not teach **the biosensor of claim 5, further comprising: a pair of terminals provided on said substrate; and a pair of electrodes provided in said sample receiving section to be spaced from each other and respectively connected to said pair of terminals.**

YAMAUCHI et al. teaches **a pair of terminals provided on said substrate; and a pair of electrodes provided in said sample receiving section to be spaced from each other and respectively connected to said pair of terminals** *(on the backside of the electrode portion 60, on the other hand, a circular first working electrode 76 and its terminal 76a are formed similar to the case of the upside, in addition to a roughly circular second working electrode 78 having the same center with and a larger size than those of the first working electrode 76, as well as its terminal 78a. Also formed on the backside is an insulating layer 74 shown by a shaded portion excluding the first working electrode 76, the second working electrode 78 and a gap between them)* in the specification column 28 lines 6-14.

YAMAUCHI et al. teaches a specific binding assay methods for performing highly accurate and quick measurements effected by the exclusion of various factor such a s temperature and changes in activity of reagents in the specification column 3 lines 15-20. Therefore, it would have been obvious to one of ordinary skill in the art to combine the teachings of DOUGLAS et al. YAMAUCHI et al.

20. Regarding Claim 7, DOUGLAS teaches **the biosensor of claim 1**,

However DOUGLAS et al. does not teach **wherein said reagent includes at least one of an antibody and an antigen.**

YAMAUCHI et al. however teaches horseradish perioxidase-labeled antihCGbeta antibody in the specification column 42 lines 45-46.

It would have been obvious to one of ordinary skill in the art to combine the biosensor of DOUGLAS et al. with the antibody of YAMAUCHI et al. as a detection means in an hCG specific binding assay device.

21. ***Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over NANKAI et al. (US 5,266,179) in view of DOUGLAS et al (US 5,843,691).***

22. Regarding Claim 12, NANKAI et al. teaches **A measurement method for measuring a test substance included in a sample by using a biosensor** *(a quantitative analysis system for measuring a specific component in biological body fluid by an amperometric method)* in claim 1 **including a substrate** *(disposable sensing means including a substrate)* in claim 21, **a sample receiving section provided on said substrate** *(a disposable sensor for receiving a sample)* in claim 2 and containing a reagent section including a reagent to be reacted with said test substance a reaction layer, including an enzyme and a mediator in claim 21 **and a moisture absorbing material changed in color through absorption of moisture, comprising the steps of:** *(In this case, when a substance 14 related to the generation of a signal substance (a combination of urate and dissolved oxygen) reaches a signal substance generator (uricase-labeled specific binding substance) 10 in a channel "b", a signal substance (hydrogen peroxide) 12 is formed. When the signal substance 12 reaches and detection means c.sub.1 or c.sub.2*

(peroxidase-immobilized part), it changes a substance related to the generation of a signal (orthodianisidine) to generate a signal (coloration). (98) Thereafter, coloration after or until a predetermined time elapse is measured at each detection means "c" by detecting absorbance or reflected light of the color or visually observing the color) in the specification column 18 lines 55-67.

h. **fitting said biosensor on a biosensor measuring apparatus (***sensor is fitted into the holder of the analyzer)* in the specification column 4 lines 67-68.

i. **determining a degree of degradation of said reagent on the basis of a degree of color change of said moisture absorbing material** *(In this case, when a substance 14 related to the generation of a signal substance (a combination of urate and dissolved oxygen) reaches a signal substance generator (uricase-labeled specific binding substance) 10 in a channel "b", a signal substance (hydrogen peroxide) 12 is formed. When the signal substance 12 reaches and detection means c1 or c2 (peroxidase-immobilized part) it changes a substance related to the generation of a signal (orthodianisidine) to generate a signal (coloration). (98) Thereafter, coloration after or until a predetermined time elapse is measured at each detection means "c" by detecting absorbance or reflected light of the color or visually observing the color)* in the specification column 18 lines 55-67.

However NANKAI et al. does not teach **measuring said test substance under measurement when the degree of degradation of said reagent is determined to be small in the determining step and stopping to measure said test substance under**

measurement when the degree of degradation of said reagent is determined to be large.

DOUGLAS et al however teaches *(a timer element, which comprises an assay area that includes, in addition to the reagent, an amount of glucose that causes the area the change color a predetermined time after the sample is applied to the strip)* in claim 30 and *(the reading can be taken at any time after timer area 42 changes color. Note that in figure 7 the color change caused by the reaction with glucose is from white to colored. However, the system could alternatively operate with an indicator dye that is destroyed by the glucose-induced oxidation, with a corresponding color change from colored to white)* in the specification column 13 lines 31-37.

It would have been obvious to one of ordinary skill in the art to combine the DOUGLAS method for measuring a fluid with a biosensor with NANKAI timer element to determine the degree of degradation of said reagent during the reaction, and to determine the ending of the reaction.

Conclusion

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANITA BUCSAY DAMRON whose telephone number is (571)270-5549. The examiner can normally be reached on Monday through Thursday 8:30 to 4:30 every other Friday 7:30 to 4:30.

24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Barbara L. Gilliam can be reached on 571-272-1330. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anita Bucsay Damron

ART UNIT 4112

/Brian Sines/
Primary Examiner, Art Unit 1797